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10/594,196

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Patrick F. Kiser

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EXAMINER

BARHAM, BETHANY P

ART UNIT

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1615

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12/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,196	<b>Applicant(s)</b> KISER ET AL.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20, 23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 23 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 2-7, 14, 18, and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/20/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Summary***

Receipt of IDS filed on 12/20/07 is acknowledged. Applicant's response filed on 9/2/09 is acknowledged. Claims 1-20, 23 and 28-30 are pending. Claims 1-20, 23 and 28-30 are rejected.

### **Election/Restrictions**

Applicant's election with traverse of Group I in the reply filed on 9/2/09 is acknowledged. The traversal is on the ground(s) that unity is not lacking in the groups and that while the Examiner "correctly identified the general inventive concept", the Examiner has "incorrectly characterized the reference...('877) does not in any way describe a polymer system that degrades upon exposure to an ejaculate". This is not found persuasive because the instant claims are drawn to a composition and intended use of that composition is not patentable, '877 teaches a polymer gel capable of responding to a change in pH by an ejaculate and neutralizing the ejaculate, the polymers (such as polyacrylics and crosslinked polymer) have a pKa of 6 and keep pH between 3-5. According to Applicant's own specification and originally presented claims polyacrylate based polymer such as those formed from acrylic acid monomers are polymers "that degrade upon exposure to an ejaculate" (pg. 7, lines 3-6), Further, the prior art teaches a composition and process for forming said composition described by applicants instant application, but applicants observation that it also 'degrades upon

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exposure to an ejaculate' does not give it patentable weight, since it is the same composition and same process of making, as adding a characterization to a prior art patented invention is not patentable. Further see "Cited as Interest" art which makes it clear that the instant water soluble polymers are well known biodegradable/erodible/degradable polymers even in the absence of "an ejaculate", thus it is an inherent property of these polymers that they degrade. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. Claims 1-20, 23 and 28-30 will be examined in the instant application. For the purpose of examination the instant claims elected polymer species is "water soluble synthetic polymer". Applicant timely traversed the restriction (election) requirement in the reply filed on 09/02/09. The requirement is still deemed proper and is therefore made FINAL.

### ***NEW OBJECTIONS/REJECTIONS***

#### ***OBJECTIONS***

Claims 2-7, 14, 18 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Currently the phrase "degradable sequence" and "degradation" do not further limit the composition comprising a polymer system.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20, 23 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims states that they are directed to a composition comprising "a polymer system", the formulation of this composition is not described beyond "water soluble synthetic polymers". What is the structure of this system? The phrase "susceptible to degradation upon exposure to an ejaculate" is intended use of the system and does not further limit or define the system in terms of structure and neither does the instant specification. There is no other support for the structure of the "polymer system" in the instant specification other than to state it is "bioresponsive to the...cavity in which they are applied" (pg. 6, lines 17-21).

Also the dependent claims directed to "a degradable sequence" does not further limit or define the water soluble synthetic polymers, what structure or chemical composition does the "a degradable sequence" have? At this time it appears to be an undefined functional limitation that only occurs when the composition is in use. The instant specification does not further define "a degradable sequence" other than to state that it "is susceptible to degradation upon contact with an ejaculate...the components of

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an ejaculate...include protein, carbohydrate, etc" (pg. 9, lines 10-15), but this is intended use of the product and not the product itself, which does not adequately describe the composition itself in terms of structure. This is a written description rejection.

Claims 1-20, 23 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a scope of enablement rejection.

The instant claims read on composition comprising; a polymer system susceptible to degradation upon exposure to an ejaculate.

Thus, the instant claims read on any water-soluble synthetic polymer. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to any water-soluble synthetic polymer, only those listed on pages 6-7 and the Examples of the instant specification.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731,8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not

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'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, the quantity of experimentation provided in the instant specification is limited to as there are no Examples of a water soluble synthetic polymer provided. The prior art teaches 6,068,851 ('851) teaches specifically that a limited group of polymers such as poloxamers and PEG are used, while others teach HPC, CMC, PEG, and polyacrylic acid such as US 2003/0211161 ('161) and trademarked Advantage-S. In fact certain water-soluble synthetic polymers are toxic in mammals such as polymers made from azodiamides, cyanos, etc, thus not every water soluble synthetic polymer is capable of being used in the instant invention. Currently no such guidance is provided in the instant specification or the instant claims.

The relative skill of those in the art is a polymer chemist (BS/MS degree). The predictability is low and since the prior art seems to be directed specifically to cellulose,

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PEG, poloxamers, polyacrylics and acrylates and not any water-soluble synthetic polymer as instant claimed. Finally, the claims are extremely broad.

Thus, based on the analysis above the conclusion that the instant claims are not enabled is inescapable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,068,851 ('851).

The instant claims are drawn to a composition comprising; a polymer system susceptible to degradation upon exposure to an ejaculate (elected polymer species: water soluble synthetic polymers).

See "Cited as Interest" art which makes it clear that the instant water soluble polymers are well known biodegradable/erodible/degradable polymers even in the



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absence of “an ejaculate”, thus it is an inherent property of these polymers that they degrade or are biodegradable.

- ‘851 teaches a gel composition comprising film forming components such as poloxamers capable of forming a barrier to pathogens and are applied to mucosae such as vaginal, cervical, rectal, etc (abstract, col. 1, lines 60-67). Poloxamers are copolymers of polyoxyethylene (PEO) and polyoxypropylene (PPO) (or a triblock of PEO and PPO) and liposomes which are pH sensitive, heat sensitive, etc such as distearoylphosphatidylethanolamine-PEG (according to the instant specification these are water soluble synthetic polymers pg. 6, lines 22-30) (col. 5, lines 48-67 and col. 6, lines 25-67). The ‘851 teaches that the gel compositions are thermoreversible and able to be in liquid form at low temp and gel form at body temp (meeting the limitations of claims 1-13 and 28-29).
- ‘851 teaches that the composition further comprises microbicides, spermicides, etc that cause a disease to be inactivated or treated and are intended to prevent STDs (abstract, col. 3, lines 50-67; col. 6, lines 4-24) (meeting the limitations of claims 14-16, 19 and 30).
- ‘851 teaches a gel compositions are applied to mucosae such as vaginal, cervical, rectal, etc and are applied to the skin of health professionals (abstract, col. 1, lines 60-67; col. 7, lines 32-34) (meeting the limitations of claims 17-18 and 23).

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- '851 teaches that a disease is inactivated or treated and are intended to prevent STDs such as HIV (abstract, col. 4, lines 1-14; col. 7, lines 9-37) (meeting the limitations of claim 20).
- It is noted that the phrase "susceptible to degradation upon exposure to an ejaculate" of instant claims 1, 17, 23 and 28 is intended use of a composition, which is not patentable and has not been considered. Further the phrase "degradable sequence" in instant claims 2-7, 18 and 28-29 does not further limit the polymer system composition.

Claims 1-20, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2003/0211161 ('161).

- '161 teaches a composition comprising polyethylene glycol (PEG) and cellulose polymers (abstract, [0038]). Delivery is taught to vaginal or oral mucosa [0047-0048]. According to '161 cellulose polymers like carboxymethylcellulose (CMC), hydroxypropylcellulose (HPC), etc contribute to viscosity and bioadhesiveness [0039, 0044], while PEG is a heat generating agent [0045]. Gels, jellies, syrups, etc are compositions of '161 [0046] and compositions of PEG and HPC are taught in Example 9: compositions 10-13 and 16 (according to the instant specification these are water soluble synthetic polymers pg. 6, lines 22-30) (meeting the limitations of claims 1-13, 17-18, 23 and 28-29).
- '161 also teaches hormones for contraceptives and spermicides [0029, 0049, 0053, 0057] (meeting the limitations of claims 14-16, 19 and 30).

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- '161 teaches a method of treating and preventing disease, as well as contraception (claims 17-18, [0029]) (meeting the limitations of claim 20).

Claims 1-20, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gynol II® (trademark 04/20/1982) as evidenced by Burruano et al (2004).

- Gynol II® is a vaginal drug composition of carboxymethylcellulose and Nonoxynol 9 and is used for delivery of a microbicide to the vaginal environment (as evidenced by abstract and Table 2 of Burruano et al).

Carboxymethylcellulose is a mucoadhesive polymer as evidenced by Burruano et al (pg. 1, col. 2) (meeting the limitations of claims 1-20, 23 and 28-30).

- It is noted that the phrase "susceptible to degradation upon exposure to an ejaculate" of instant claims 1, 17, 23 and 28 is intended use of a composition, which is not patentable and has not been considered. Further the phrase "degradable sequence" in instant claims 2-7, 18 and 28-29 does not further limit the polymer system composition.

Claims 1-20, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Advantage-S® (trademark 02/29/2000) as evidenced by Burruano et al (2004).

- Advantage-S® is a contraceptive gel of polyacrylic acid (polycarbophil) and Nonoxynol 9 and is used for delivery of a microbicide to the vaginal environment (as evidenced by abstract and Table 2 of Burruano et al).

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Carboxymethylcellulose is a mucoadhesive polymer as evidenced by Burruano et al (pg. 1, col. 2; pg. 5, col. 2) (meeting the limitations of claims 1-20, 23 and 28-30).

- It is noted that the phrase “susceptible to degradation upon exposure to an ejaculate” of instant claims 1, 17, 23 and 28 is intended use of a composition, which is not patentable and has not been considered. Further the phrase “degradable sequence” in instant claims 2-7, 18 and 28-29 does not further limit the polymer system composition.

Claims 1-20, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,962,419 ('419).

- '419 teaches compositions comprising a macrolide antibiotic and a polymer (abstract) for treatment in diseases caused by bacteria (col. 1, lines 6-7). Particular antibiotics disclosed are kitasamycin, erythromycin, spiramycin, josamycin and antibiotic SF-837 which can be applied/administered orally, rectally or vaginally (col. 1, lines 11-15). Particular acid insoluble polymers disclosed are cellulose acetate phthalate and hydroxypropyl methylcellulose phthalate (col. 1, lines 59-60). The examples also demonstrate the combination of an antibiotic and cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate (meeting the limitations of claims 1-20, 23 and 28-30).
- It is noted that the phrase “susceptible to degradation upon exposure to an ejaculate” of instant claims 1, 17, 23 and 28 is intended use of a composition,

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which is not patentable and has not been considered. Further the phrase “degradable sequence” in instant claims 2-7, 18 and 28-29 does not further limit the polymer system composition.

### ***Cited As Interest***

Nakamiya et al (1997) teaches that PEG degrades in 20 hours in the absence of enzymes and faster with enzymes present, as was similar with polyacrylic acid (abstract).

US 7,488,343 teaches that biodegradable/erodible material used in therapeutic compositions includes water soluble polymers such as polyvinyl alcohol, polyacrylic acid, carboxymethyl cellulose, polyethylene glycol, etc (col. 7, lines 26-39).

US 6,378,526 teaches that biodegradable and biocompatible polymers include water soluble polymers such as PEG, PVP, cellulose polymers like HPC, CMC, etc, and polyacrylic acids (col. 9, lines 23-40).

US 4,988,512 teaches that water soluble polymers are biodegradable and in mucous tend to degrade over 1 or more days and lists polymers like acrylate polymers, cellulose polymers (col. 3, lines 43-55).

US 6,403,597 teaches that water soluble polymers include acrylic acid polymers, carboxypolyalkylenes, PEG, HPC, CMC, etc (col. 15, lines 61-col. 16, lines 40, col. 17, lines 15-35, etc) and that the polymers erode/degrade over time from 10 min-24 hrs (col. 16, lines 60-64, col. 20, lines 7-11; col. 23, lines 23-28)

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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